



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94756d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3003055443

May 19, 2004

Harold Schenker, President
Sunsweet Growers Inc.
901 N. Walton Avenue
Yuba City, California 95993

Dear Mr. Schenker:

The U.S. Food and Drug Administration (FDA) collected samples of the product, SUNSWEET® brand Prune Juice, 32 FL OZ (1QT) 946mL, for laboratory analysis on October 9, 2003. The samples were collected from your facility at 901 N. Walton Avenue, Yuba City, California. A copy of the product label is enclosed.

FDA's sample analysis of January 14, 2004 revealed sub-potency in the mineral nutrient, iron, compared to the amount declared on the label. FDA laboratory results are as follows:

Nutrient	Analysis	Label Declaration	Found	% of Declared
Iron	Original	10% Daily Value	2.92% Daily Value	29.2
Iron	Check	10% Daily Value	3.39% Daily Value	33.9
Iron	Additional	10% Daily Value	2.42% Daily Value	24.2

The product is misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(a)(1)) in that the labeling is false and misleading. The amount of iron declared on the label does not comply with the requirements of Title 21, Code of Federal Regulations, Section 101.9(g)(4)(ii) [21 CFR 101.9(g)(4)(ii)] because the amount of iron present is less than 80 percent of the amount declared.

As a manufacturer of food products, it is your responsibility to ensure that all of your products are manufactured and labeled in accordance with applicable statutes and regulations.

If you reply to this letter, your response should be directed to Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Barbara J. Cassens
District Director
San Francisco District

Enclosure: Label for SUNSWEET® brand Prune Juice, 32 FL OZ (1QT) 946mL

cc: VIA FEDERAL EXPRESS
Steven J. Kollars, Director, Technical Service and Quality Assurance